

disclaimer of the subject matter contained therein, as outlined in Appendix A, attached herewith.

**REMARKS**

After entry of the above amendment, claims 3-6 and 8 will be pending in this application. The amendment does not add any new matter. Accordingly, its entry is respectfully requested.

**1. Rejection of claims 1-6 under 35 U.S.C. §102(b)**

The Official Action states that claims 1-6 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 01/72756 (the '756 application).

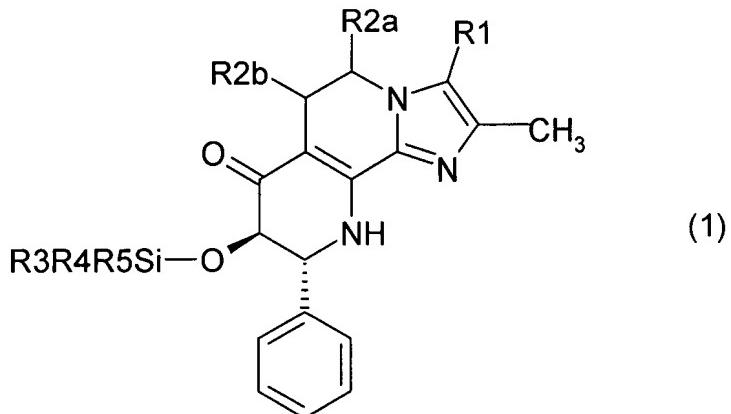
**Response**

First, applicants respectfully point out to the Examiner that claims 1-2 have been canceled without prejudice to or disclaimer of the subject matter contained therein, rendering the basis of this rejection moot as to these claims.

Regarding the rejection of claims 3-6, applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131. The elements

must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

The presently claimed invention is related to a compound of the formula 1,



in which

R<sub>1</sub> is methyl,

R<sub>2a</sub> and R<sub>2b</sub> are both hydrogen or together denote a bond,

R<sub>3</sub> is tert-butyl,

R<sub>4</sub> is methyl and

R<sub>5</sub> is methyl,

or a salt thereof.

In contrast, the '756 application does not teach the presently claimed compound. Instead, the '756 application teaches a compound with possibly "a suitable silyl radical" protecting the R<sub>5a</sub> or R<sub>5b</sub> substituent. Page 20 of the '756 application discloses that the "suitable silyl radical" may be trimethylsilyl (TMS) and does not disclose any other

alternative silyl radicals, such as the presently claimed compound containing the tert-butyl-dimethyl-silyl (TBDMS) protecting group.

Further, with regards to claims 4 and 6, applicants respectfully note that the '756 application does not disclose a compound wherein the presently claimed R2a and R2b substituents are both hydrogen and not a double bond.

As such, the '756 application does not teach each and every element of the presently claimed invention and is insufficient to establish a *prima facie* case of anticipation. As such, applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 3-6.

## **2. Rejection of claims 1-6 under 35 U.S.C. §102(b)**

The Official Action states that claims 1-6 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 01/72754 (the '754 application).

### **Response**

First, applicants again respectfully point out to the Examiner that claims 1-2 have been canceled without prejudice to or disclaimer of the subject matter contained therein, rendering the basis of this rejection moot as to these claims.

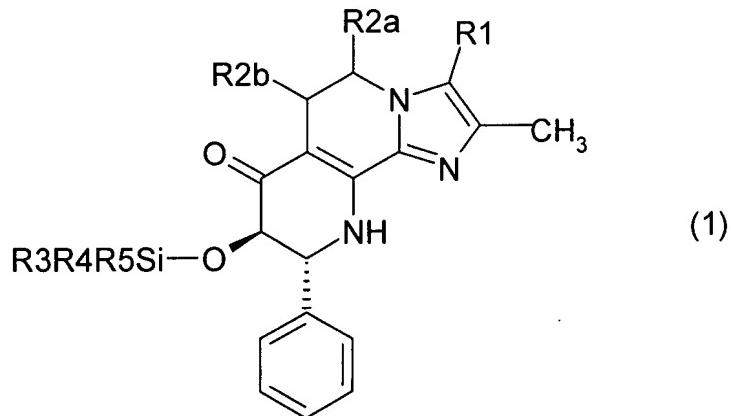
Regarding the rejection of claims 3-6, applicants respectfully traverse this rejection. As stated above, the test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131.

The identical invention must be shown in as complete detail as is contained in the claim.

*Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131.

The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

The presently claimed invention is related to a compound of the formula 1,



in which

R1 is methyl,

R2a and R2b are both hydrogen or together denote a bond,

R3 is tert-butyl,

R4 is methyl and

R5 is methyl,

or a salt thereof.

In contrast, the '754 application does not teach the presently claimed compound.

Instead, the '754 application teaches a compound with possibly "a suitable silyl radical"

protecting the R5a or R5b substituent. Page 24 of the '754 application discloses that the "suitable silyl radical" may be trimethylsilyl (TMS) and does not disclose any other alternative silyl radicals, such as the presently claimed compound containing the tert-butyl-dimethyl-silyl (TBDMS) protecting group.

Further, with regards to claims 4 and 6, applicants respectfully note that the '754 application does not disclose a compound wherein the presently claimed R2a and R2b substituents are both hydrogen and not a double bond.

As such, the '754 application does not teach each and every element of the presently claimed invention and is insufficient to establish a *prima facie* case of anticipation. As such, applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 3-6.

### **3. Rejection of claims 1-8 under 35 U.S.C. §102(b)**

The Official Action states that claims 1-8 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/42707 (the '707 application).

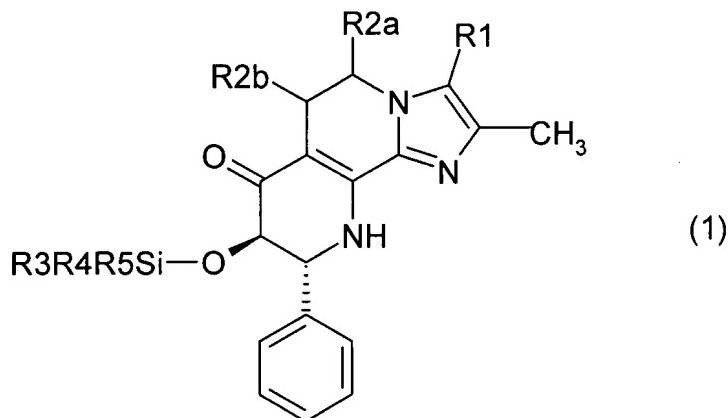
#### **Response**

First, applicants again respectfully point out to the Examiner that claims 1-2 and 7 have been canceled without prejudice to or disclaimer of the subject matter contained therein, rendering the basis of this rejection moot as to these claims.

Regarding the rejection of claims 3-6 and 8, applicants respectfully traverse this rejection. As stated above, the test for anticipation is whether each and every element as

set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

The presently claimed invention is related to a compound of the formula 1,



in which

R1 is methyl,

R2a and R2b are both hydrogen or together denote a bond,

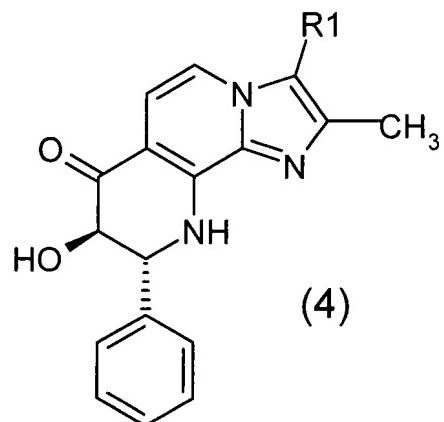
R3 is tert-butyl,

R4 is methyl and

R5 is methyl,

or a salt thereof.

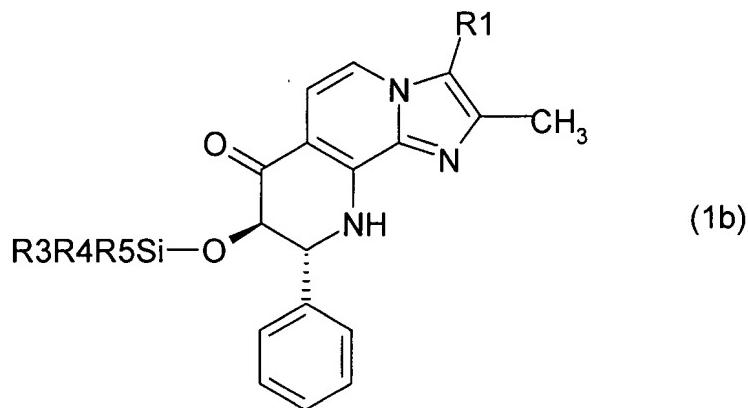
Further, the presently pending claims are directed to a process of preparing a compound of formula 4



in which

R1 is methyl,

comprising hydrolyzing the compound of formula 1b



in which

R1 is methyl,

R3 is tert-butyl,

R4 is methyl and

R5 is methyl,

or a salt thereof.

In contrast, the '707 application does not teach the presently claimed compound which has the specific protecting group TBDMS or process of preparing this compound. Instead, the '707 application teaches protecting groups generally.

Further, with regards to claims 4 and 6, applicants respectfully note that the '707 application does not disclose a compound wherein the presently claimed R2a and R2b substituents are both hydrogen and not a double bond.

As such, the '707 application does not teach each and every element of the presently claimed invention and is insufficient to establish a *prima facie* case of anticipation. As such, applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 3-6 and 8.

#### **4. Rejection of claims 1-8 under 35 U.S.C. §103(a)**

The Official Action states that claims 1-8 are rejected under 35 U.S.C. §103(a) as being unpatentable over the '756 application, the '754 application and the '707 application as recited above in sections 1-3.

#### **Response**

First, applicants again respectfully point out to the Examiner that claims 1-2 and 7 have been canceled without prejudice to or disclaimer of the subject matter contained

therein, rendering the basis of this rejection moot as to these claims.

Regarding the rejection of claims 3-6 and 8, applicants respectfully traverse this rejection. The Examiner has not shown a *prima facie* case of obviousness with respect to the presently rejected claims.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court recently held in KSR International Co. v. Teleflex Inc. et al., Slip Opinion No. 04-1350, 550 U. S. \_\_\_\_ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (KSR, *supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Amgen Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. In re Wilson,

165 USPQ 494, 496 (C.C.P.A. 1970).

a. The Examiner has failed to provide a reference that teaches or suggests all limitations of the claims as required by *In re Wilson*.

None of the cited references, alone or in combination, teach or suggest every limitation of the presently pending claims. As outlined above, the cited references either teach protecting groups generally, or teach a different protecting group trimethylsilyl (TMS), and not the specific protecting group tert-butyl di-methyl silyl (TBDMS) present on the claimed compound. Thus, none of the cited references, alone or in combination, teach or suggest every limitation of the presently pending claims as required by *In re Wilson*.

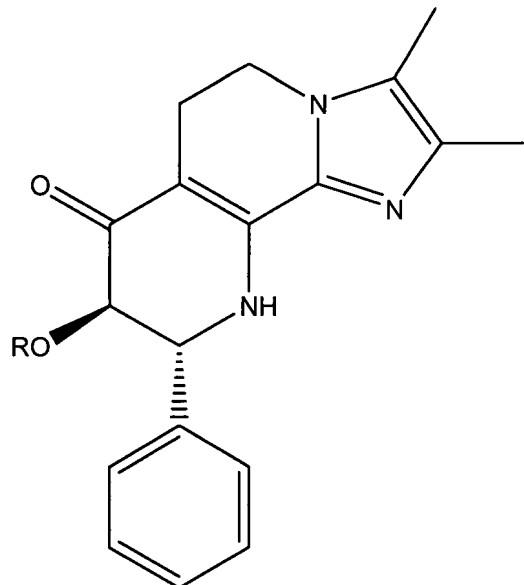
Accordingly, the Examiner has failed to carry her burden of demonstrating a *prima facie* case of obviousness. However, if the Examiner insists that she has demonstrated a *prima facie* case of obviousness, applicants respectfully submit that the data present in the attached Declaration under 37 CFR 1.132 has rebutted this *prima facie* case of obviousness.

b. Applicants have submitted evidence herewith of the unexpectedly superior properties of the presently claimed protecting group

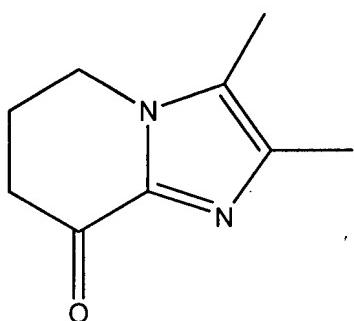
Applicants have submitted herewith an executed Declaration under 37 CFR 1.132 which clearly demonstrates the superiority of the presently claimed protecting group, TBDMS, over the protecting group cited in the prior art, TMS.

The Declaration outlines that three separate reactions were conducted in attempts

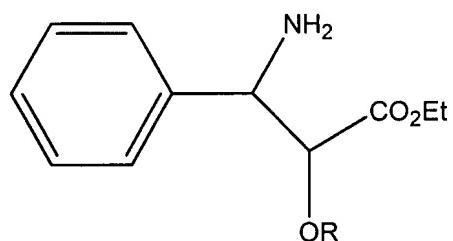
to prepare the compound of formula



by reacting a compound of the formula



with a compound of the formula



wherein the substituent R was either

- 1) H;
- 2) trimethylsilyl (TMS); or
- 3) tert-butyl-dimethyl silyl (TBDMS).

Upon completion of each reaction, it was surprisingly found that the protecting group taught in the prior art, TMS, was unstable under the reaction conditions necessary to obtain the desired compound and failed to yield any of the product due to its instability.

In contrast, it was discovered that the reaction using the presently claimed compound with protecting group TBDMS was the only successful reaction which yielded any product. The compound with the TBDMS protecting group was stable under the harsh reaction conditions necessary to obtain the desired compound.

As such, applicants have clearly shown the unexpectedly superior properties of the presently claimed compound containing the TBDMS protecting group in this side-by-side comparison over the compound containing the TMS protecting group which is taught in the prior art. Accordingly, the *prima facie* case of obviousness, if still standing, has been properly rebutted.

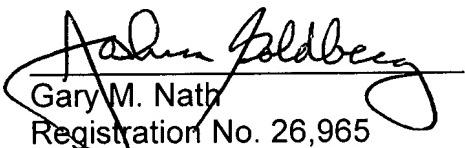
As such, applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 3-6 and 8.

**CONCLUSION**

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw all rejections and objections and allow all pending claims in this application. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,  
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